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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,356	01/26/2005	Christopher Bruce Alexander Whitelaw	102286.155US1	1380
23483	7590	09/21/2007		
WILMER CUTLER PICKERING HALE AND DORR LLP 60 STATE STREET BOSTON, MA 02109			EXAMINER MITCHELL, LAURA MCGILLEM	
			ART UNIT 1636	PAPER NUMBER
			NOTIFICATION DATE 09/21/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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## Office Action Summary

Application No.

10/522,356

Applicant(s)

WHITELAW ET AL.

Examiner

Laura M. Mitchell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 22-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 22-35 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

***Supplemental Election/Restrictions***

It is noted that in response to the previous restriction requirement mailed 3/23/2007, Applicants have elected Group IV (claims 23-35) drawn to a method of detecting a gene activation event comprising the use of a peptide-tagged lipocalin reporter expressed in a **transgenic non-human animal**, wherein the lipocalin is  $\beta$ -**lactoglobulin**. Applicants have also elected the species of **SEQ ID No. 1** which is EQKLISEEDL from c-myc, and also elected the promoter element **Cyp1a1**.

On further consideration, a further restriction/election is required.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: Gene activation event that is:

- A.) Induction of a toxicological stress.
- B.) Metabolic changes.
- C.) Diseases that are a result of viral bacterial, fungal and parasitic infection.
- D.) Cancer, inflammatory disease, cardiovascular disease, neurological disease and disease with a genetic basis.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims

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subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claim 22 corresponds to A – D.

Claim 33 corresponds to A.) Induction of a toxicological stress.

Claim 34 corresponds to C.) viral bacterial, fungal and parasitic infection/ disease.

Claim 35 corresponds to D.) Cancer, inflammatory disease, cardiovascular disease, neurological disease and disease with a genetic basis.

The following claim(s) are generic: 22.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species lack unity of invention and lack a special technical feature that defines a contribution over the prior art because the putative special technical feature of Group IV is a transgenic animal that expresses a construct comprising a member of the lipocalin family was known in the prior art (see Farini and Whitelaw, 1995, Mol. Gen. Genetics, Vol.246, No. 6 abstract). Farini and Whitelaw teach transgenic mice comprising genomic constructs comprising the ovine beta-lactoglobulin (BLG) gene (see abstract).

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Each of the species comprises a method of detecting a particular gene activation event comprising the use of the genomic construct comprising BLG. The technical feature of species A that distinguishes it from the other species is detection of toxicological stress to the transgenic animal, which is not found in species B-D. The technical feature of species B that distinguishes it from the other species is detection of metabolic changes in the transgenic animal, which is not found in species A or C-D. The technical feature of species C that distinguishes it from the other species is detection of diseases that result from viral bacterial, fungal and parasitic infection, which is not found in species A-B or D. The technical feature of species D that distinguishes it from the other species is detection of cancer, inflammatory disease, cardiovascular disease, neurological disease or a genetic disease, which is not found in species A-C.

The transgenic animal expressing a construct comprising BLG could be used in a method to detect any of the distinctive species of gene activation and would not overlap with the other species of gene activation. The outcome of each of the species is distinct from one another. For example, the outcome of the method of species A would be a mouse with diagnosed toxicological stress, which is distinguished from the outcome of the method of species D which would be a diagnosis of a genetic disease.

A search for one of the species of gene activation would not encompass a search for any of the other species and a search for all would therefore constitute a burdensome search.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

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requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura M. Mitchell whose telephone number is (571) 272-8783. The examiner can normally be reached on M-F 8:00-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura M. Mitchell, PhD  
Examiner  
9/17/2007

CELINE QIAN, PH.D.  
PRIMARY EXAMINER

